

DETAILED ACTION

Applicants' arguments, filed July 8, 2011, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claims 1, 3-6 and 8-13 are pending.

Claims 11 and 12 are withdrawn.

This action is Non-final.

Claim Objections

Claim 13 is objected to because of the following informalities: the phrase "selected from the group" should follow the phrase "polyvinyl compound" in line 3. Appropriate correction is required.

Claim Rejections - 35 USC § 103

New Rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-6, 8-10 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Helleberg et al. (US Patent No. 6,342,524, previously disclosed).

Helleberg et al. disclose a composition for the treatment of glaucoma and ocular hypertension, comprising the administration of a prostaglandin analog and a prostaglandin synthesis inhibitor (Abstract). Helleberg et al. disclose the preferred FP-agonist is latanoprost and the compositions are in the form of an emulsion (column 7,

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lines 54-55 and column 8, line 66). Hellberg et al. further disclose the ophthalmic emulsion composition further comprise CREMOPHOR® EL, which is a polyoxyl 35 castor oil and meets the limitation of an oil of instant claim 6 (column 8, lines 54-56 and 66); and viscosity building agents, i.e. polyvinyl alcohol, which meets the limitation of water soluble polymer of instant claims 4, 5 and 13 (column 9, line 1).

The prior art does not appear to provide sufficient specificity, i.e., involves too much “picking and choosing” to give rise to anticipation. See *Corning Glass Works v. Sumitomo Elec.*, 868 F.2d 1251, 1262 (Fed. Circ. 1989). That being said, it must be remembered that “[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect.... the combination is obvious”. *KSR v. Teleflex*, 127 S.Ct. 1727, 1740 (2007) (quoting *Sakraida v. A.G. Pro*, 425 U.S. 273, 282 (1976)). Consistent with this reasoning, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have selected the various combinations of features claimed from within the prior art disclosure (specifically, the oil, i.e. polyoxyl 35 castor oil, prostaglandin derivative and water-soluble polymer, i.e. polyvinyl alcohol) to arrive at the instantly claimed subject matter.

Allegations of Unexpected Results

In regard to Applicant's alleged unexpected results, Applicant asserted in its response filed January 31, 2011 that an emulsion of latanoprost showed excellent

stability of the drug in an aqueous composition as shown in Table 2 of the instant specification and that a person of skill in the art can expect that other prostaglandin derivatives recited in claim 1 would be stabilized by emulsifying a formulation according to the latanoprost composition. Applicant argues in the response filed July 8, 2011 that the polyethoxylated castor oil of Schneider (US Patent 5,631,287) is a non-ionic surfactant not an oil.

The Examiner submits that Applicant's Exhibit 4 (BASF Technical Leaflet for Cremophor® EL) discloses on p. 2, properties that Cremophor® EL is a pale yellow, oily liquid; therefore it is not clear how Applicant can consider Cremophor® EL as "not an oil".

As previously asserted, the evidentiary reference Schneider was used to show that prostaglandins have low water solubility and are generally unstable; however, the stability can be increased with polyethoxylated castor oil. Furthermore, the stabilizing effect of the polyethoxylated castor oil increases with increasing the concentration of the oil, which is shown in FIG. 1 (Abstract, column 6 lines 16-22). The stability is shown in FIG. 1. It is seen that when polyoxyethylated castor oil is added to the composition, the concentration of PG is about 90% of the initial concentration after about 4 weeks of storage at 65°C.

Applicant's alleged unexpected results wherein it was recognized that an oil-in-water emulsion formulating latanoprost together with a medium chain fatty acid triglyceride and water-soluble polymer suppressed the degradation of latanoprost, do not appear to be unexpected. Specifically since it was shown by Schneider that oils

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increase the stability of prostaglandins and the concentration of the oil is a "result effective" variable, i.e. increasing the concentration increases the stability. As discussed above, the stability shown in FIG. 1, when polyoxyethylated castor oil is added to the composition, the concentration of PG is about 90% of the initial concentration after about 4 weeks of storage at 65°C, thereby showing the increase in stability. Therefore, one of ordinary skill in the art would reasonably expect the oil-in-water emulsion of Hellberg, which comprises the same polyoxyl 35 castor oil of Schneider, would have an increased stability of the prostaglandin.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANNETTE HOLLOMAN whose telephone number is (571)270-5231. The examiner can normally be reached on Mon-Fri 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/N. H./
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612